Maryland Board of Pharmacy
Public Board Meeting
Minutes

Date: October 17, 2012

Name	Title	Present	Absent	Present	Absent
Board Committee					
Bradley-Baker, L.	**Commissioner/Treasurer**	✓		**3**	**1**
Chason, D.	**Commissioner**	✓		**4**	**0**
Finke, H.	**Commissioner**	✓		**4**	**0**
Gavgani, M. Z.	**Commissioner**	✓		**3**	**1**
Hammonds, S.	**Commissioner**	✓		**3**	**1**
Handelman, M.	**Commissioner**	✓		**4**	**0**
Israbian-Jamgochian, L.	**Commissioner**	✓		**3**	**1***
Matens, R.	**Commissioner**		✓ **jury duty***	**2**	**2**
Souranis, M.	**Commissioner/President**	✓		**4**	**0**
St. Cyr, II, Z. W.	**Commissioner**	✓		**4**	**0**
Taylor, D.	**Commissioner**	✓		**4**	**0**
Taylor, R.	**Commissioner/Secretary**	✓		**3**	**1**
Board Counsel					
Bethman, L.	**Board Counsel**	✓		**4**	**0**
Felter, B.	**Staff Attorney**	✓		**4**	**0**
Board Staff					
Naesea, L.	**Executive Director**	✓		**4**	**0**
Wu, Y.	**Compliance Manager**	✓		**3**	**1**
James, D.	**Acting Licensing Manager**	✓	✓	**2**	**0**
Gaither, P.	**Administration and Public Support Manager**	✓		**3**	**1**
Jeffers, A.	**Legislation/Regulations Manager**	✓		**4**	**0**
Kolapalli, P	**MIS Project Manager**	✓		**4**	**0**

***excused**

Subject	Responsible Party	Discussion	Action Due Date (Assigned To)	Results
I. Executive Committee Report(s)	A. M. Souranis, Board President	*Members of the Board with a conflict of interest relating to any item on the agenda are advised to notify the Board at this time or when the issue is addressed in the agenda.* 1. M. Souranis, President, called the Public Meeting to order at 9:42 a.m. 2. M. Souranis requested all meeting attendees to introduce themselves, to please sign the guest log and to indicate whether they would like continuing education credits before they leave the meeting. 3. Members of the Board with any conflict of interests relating to any item on the agenda were advised to notify the Board. 4. M. Souranis reported that all handouts are to be returned by attendees when they leave the meeting. 5. Review and approval of September 19, 2012 public board meeting minutes.	Motion to accept minutes as submitted made by D. Taylor. Motion was seconded by R. Taylor.	Motion was approved
II. Executive Director Report	A. L. Naesea	• **Operations Update** – L. Naesea announced that one of the Board's inspectors, Yin Chan, has resigned her position effective October 11, 2012. A freeze exempt to hire a replacement has been requested and the Board anticipatesreceiving approval for the freeze exempt request before the end of the month. There was some discussion regarding replacing Yin Chan's position with a pharmacist, but it was decided that in addition to filling the pharmacy technician vacancy a second FTE pharmacist inspector is needed to support the anticipated increase in pharmacies being inspected (up to 100), based	Motion by L. Israbian-Jamgochian to add an additional pharmacist staff member to work in Compliance Department. Motion was seconded by S. Hammonds.	Motion was approved.

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		on requiring satellite pharmacies associated with hospitals to acquire separate pharmacy permits. A freeze exemption has been submitted for the licensing manager position and Doris James has been assigned as the acting licensing manager. Once the Board receives approval for the freeze exemption the Board will move forward in filling that position. The MIS Manager position has been recruited with an anticipated start date of November 14, 2012. The Computer Network Specialist position closed recruitment on September 29, 2012 and interviews will begin when the Board receives the eligibility lists from the DHMH. We are now in week three with the new MIS automated system, which went live on October 5, 2012. As noted previously, any new system will have bugs that need to be addressed; the MIS new automated system is no different. If any licensee is having trouble with the E-Gov system and need a verification letter for their employed please contact the Board and the Board will be glad to assist. • **Meeting Updates** : Commissioners H. Finke, L. Israbian-Jamgochian and L. Naesea all attended the NABP District Meeting in Skytop, PA this past weekend beginning Sunday, October 14 through Tuesday, October 16, 2012. L. Naesea introduced the Board's current student intern, Andrew Clayborne who attended a sub-committee working on the format of prescriptions assuring against diversion and theft, etc. The sub-committee will develop recommendations for consideration by their respective board/unit before submitting them formally to the CDC Integrated Committee. The student intern will presented a report at the sub-committee meeting to support the formulation of its recommendations. He concluded that requiring the		

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		current Maryland Medicaid requirements for prescription pad be me by all prescribers would save physicians from needing more than one set of pads. (one for Medicaid patients and another set for privately insured patients). Following discussion among the Commissioners the Board decided to refer the matter to the Practice Committee for further review and recommendation to the full BOP. • **NABP District I & II Meeting report by L. Israbian-Jamgochian:** • District I and II NABP meeting took place this year October 14-16 in Pennsylvania. There were around 100 attendees. Sue Kziacek was elected as District II rep to run for elections in May at the annual meeting. District II voted to continue the process to obtain tax exempt status and three Board members were elected. The College of pharmacies reported that we have right now 129 School of pharmacies. 2 resolutions were passed. One was on Pharmacy Compounding Sterile Products and was on Returns of medications to wholesalers. The two resolutions will be e-mailed to Board members.		
C. MIS	P. Kolapalli, MIS Program Director	The new automated system is now operational and allows for pharmacists, pharmacist technicians and wholesale distributors to renew licenses and registrations on-line. As of October 15, 2012 the BOP has received 158 on-line renewals transactions through the E-gov application of the new automated system. The BOP has encountered problems accepting American Express and Discover credit cards and will not accept these credit cards. Presently, the Board only accepts payments from Visa or Master Card. The new systemis still working out a few challenges with the vendor. The Board is also compiling requirements for initiation of Phase II in 2013. There was discussion among the Board Commissioners concerning the feasibility and propriety of users being able to print		

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		their own license once they have completed the on-line renewal process in future years. It was recommended that the matter be referred to the Practice Committee for report and recommendation to the full Board.	Motion by H. Finke to refer issue of users being able to print their licenses on-line after completing renewal process to the Practice Committee. Motion seconded by L. Israbian-Jamgochian.	Motion was approved.
D. Licensing	D. James, Acting Manager	Monthly Statistics for September 1 through September 25, 2012. Computer system was shut down on September 26, 2012 due to conversion to new SQL database system. <u>Total Pharmacists: 9031</u> In-state 6251 out-of-state 2780 New 31 (10 in state and 21 out-of-state) Renewed 319 (219 in state and 100 were out-of-state) Vaccines Certified : 3161(66 new) <u>Total Pharmacy Technician Registrations: 8918</u> New 49; Pending 101 Student Exemptions: 533 <u>Technician Training Programs</u>: New 1 Approved 2 Under Review 2 <u>Total Pharmacies</u>: 1845 Instate 1194 570 out-of-state Waiver 81 New 12(5in-state and 7 out-of-state)		

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E. Compliance	Y. Wu, Manager Gil Cohen, PEAC	1. Monthly Statistics for September, 2012 <u>Complaints & Investigations</u>: <u>New</u> 20 Resolved 40 (16 formal disciplinary actions and zero summary suspension) <u>Inspections:</u> 120 _Annual 108 Opening 7 Relocation 1 Closing 2 (performed by the Division of Drug Control) 2. PEAC Update – 16 current cases year to date New Self-referred pharmacists 2 New Referred pharmacy student 1		
F. Legislation & Regulations	A. Jeffers	**<u>MEETINGS:</u>** **<u>Anna Jeffers reported on the following meeting:</u>** **<u>1) September 24th meeting regarding the increase in the dispensing fee regulations for Dentists, Physicians and Podiatrists. Fran Phillips, Marie Grant, Board Execs and Jennifer Newman.</u>** DDC will send an initial letter to dispensing prescribers to describe the new law and request that dispensing prescribers notify their respective boards if they no longer want to have a dispensing permit.		

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		2) October 30th - two meetings scheduled: a) HGO Chair - to discuss 2013 legislative initiatives; and b) HGO Committee - Briefing on Drug Shortages 3) November 7th – House and Government Operations Committee briefing on New England Compounding Company and the meningitis outbreak. **LEGISLATION:** **Meetings are being scheduled to meet with Chairman Hammen and Chairman Carter Conway.** **LEGISLATIVE REPORTS** 1) **Maryland Board of Pharmacy Wholesale Distributor Permitting and Prescription Drug Integrity Act Sixth Annual Report to the Governor and the General Assembly** Board approval requested for the Sixth Annual Wholesale Distributor Report. **FINAL DRAFT - Report WholesaleDist Program 092612** **The Board approved the report.** **2) Report on the Implementation and Use of Sanctioning Guidelines as required by Chapters 533 and 534 of the Act of the General Assembly of 2010** **FINAL Report to EHEHGO on Sanctioning Guidelines**	Motion by Legislation/Regulations Committee to approve Sixth Annual Wholesale Distributor Report. Motion seconded by M. Gavgani.	Motion was approved.

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		101712 **The Board approved the report after a discussion of the proposed regulations and the Board responses to the formal comments.** **REGULATIONS:** **10.34.03 – Inpatient Institutional Pharmacies –**Under consideration by the Practice Committee. **10.34.06 Reporting Pharmacist's and Pharmacy Technician's Mailing Address and Location of Employment** Board approval requested to add pharmacy technician's to this chapter **DRAFT 10.34.06 100312** **The Board approved the proposal for publication.** **10.34.11 - Disciplinary Monetary Penalties, and Civil Fines** Published August 24, 2012. Two official comments received: **Formal Comment - MPhA – 092412** **Formal Comment 10.34.11_omnicare_com_** **Draft Bd Response – 10.34.11 – MPHA** Thank you for submitting a comment to the Maryland Board of Pharmacy (the "Board") concerning the proposal for COMAR 10.34.11 Disciplinary Sanctions, Monetary Penalties, and Civil Fines, published in 39:17 Md.R. 1159 – 1166 (August 24, 2012).	Motion by Legislation/Regulations Committee to approve Final Report to EHEEGO on Sanctioning Guidelines. Motion seconded by D. Taylor. Motion by Legislation/Regulations Committee to approve adding pharmacy technicians to COMAR 10.34.06 requiring the reporting of mailing address and location of employment. Motion seconded by M. Gavgani.	Motion was approved. Motion was approved.

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		"The Board appreciates your concern that some pharmacists may not feel that they are judged by their peers when subject to the Board's disciplinary proceedings. The composition of the Board is set in statute and provides for Board members from a variety of practice settings including chain store pharmacies, independent pharmacies, acute–care hospital pharmacies, long–term care facility pharmacies, home infusion/home care service pharmacies, pharmacists at–large; and consumer members. The individuals who serve on the Board use their knowledge and experience from these practice settings to further the mission of the Board and to ensure fairness in deliberations concerning practice and disciplinary matters. Although not all the Board members have experience in all the practice areas, the Board does consist of members who share the concerns of pharmacists in general and also share the concerns of the Board members' respective practice areas. Nonresident mail order pharmacies are subject to the disciplinary process as any permit holder. The Board's jurisdiction over the nonresident pharmacies was expanded in the 2012 Legislation Session to give the Board greater power to discipline nonresident pharmacies if they violate certain required standards in the Maryland Pharmacy Act. That legislation is available for your review at the following link: http://mlis.state.md.us/2012rs/chapters_noln/Ch_182_sb0132T.pdf Keep in mind that the Board's disciplinary process is complaint driven and the Board investigates every complaint received. With the new law, more complaints concerning nonresident mail order pharmacies will fall within the Board's jurisdiction and may be investigated and pursued by the Board. The Board would like to thank you again for your thorough reading of, and comments to, the published proposal for COMAR 10.34.11	Motion by Legislation/Regulations Committee to approve the draft responses to MPhA and MACDS. Motion was seconded by D. Taylor.	Motion was approved.

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		Disciplinary Sanctions, Monetary Penalties, and Civil Fines. The Board considered your comments at the October 17, 2012 Board Meeting and voted to adopt COMAR 10.34.11 as proposed. **Draft Bd Response – 10.34.11 – MACDS** Thank you for submitting a comment to the Maryland Board of Pharmacy (the "Board") concerning the proposal for COMAR 10.34.11 Disciplinary Sanctions, Monetary Penalties, and Civil Fines, published in 39:17 Md.R. 1159 – 1166 (August 24, 2012). The Board appreciates your concern with the potential severity of the penalties set forth in the proposed regulations. Please be advised that the sanctioning guidelines included in this proposal are for public sanctions for pharmacists, pharmacies, wholesale distributors and pharmacy technicians. The penalties in the sanction guidelines offer various ranges of sanctions that the Board will be required to stay within depending on the circumstances and the facts of the case. You had specifically requested that "reprimands" be imposed when infractions have not been severe. Reprimands are within the sanctioning guidelines for pharmacists, pharmacy technicians, and wholesale distributors, but the Maryland Pharmacy Act does not allow for reprimands of a permit holder. Keep in mind that many times the Board resolves disciplinary matters through preliminary non-public actions. Those resolutions are not public and the sanctions imposed for non-public actions have not been included in the proposal published in the Maryland Register. The Board has the ability, depending on the circumstances, to issue a non-public Letter of Education or Letter of Admonishment. Oftentimes these letters will educate a licensee, who may not have been fully familiar with the law, and perhaps require a licensee to complete continuing education courses to prevent a similar violation from occurring in the future. It is not the Board's intention, nor the intent of the legislature who mandated these regulations, to impose the most severe penalties available. The intent of these regulations is to provide the public, licensees, permit holders, and registrants with a range of sanctions that may be imposed. The Board would like to thank you again for your thorough reading of, and comments to, the published proposal for COMAR 10.34.11		

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		Disciplinary Sanctions, Monetary Penalties, and Civil Fines. The Board considered your comments at the October 17, 2012 Board Meeting and voted to adopt COMAR 10.34.11 as proposed. Board approval requested for responses to the comments and to adopt the revisions as proposed. **The Board approved the responses above.** Additionally, would the Board like an effective date as soon as possible or is a delayed timeframe requested for implementation? The Board approved an effective date as soon as the process allows.**10.34.14 – Opening and Closing of Pharmacies and 10.34.30 – Change to Permit – Pharmacy or Distribution Permit Holder.** Proposal released for informal comment 9/25/12 through 10/12/12. Comments to be considered at the 10/31/12 Practice Committee Meeting. **10.34.22 – Licensing of Wholesale Prescription Drug or Device Distributors –** Three Informal Comments received. **Informal Comment from Utah Medical** **Another informal comment from Utah Medical 091012** **Informal comment -Jennifer Schneider - State Licensing Services** **Maryland.gov Mail - Re_ Release for INFORMAL COMMENT - Chandra Mouli 082112** Board approval requested for template response to the informal comments. **The Board approved the template response below:**		

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		Draft Bd Response for Inform Cmts Wholesale Dist - Utah 100112 **Draft Bd Response for Inform Cmts Wholesale Dist - SLS 100112** **Draft Bd Response for Inform Cmts Wholesale Dist - DDC 100112** Thank you for offering informal comments for the Maryland Board of Pharmacy's ("Board") proposed revisions to COMAR 10.34.22 Licensing of Wholesale Prescription Drug or Device Distributors. The Board considered all the informal comments received and has revised the proposal to reflect those comments and also clarifications and recommendations by the Board's Practice Committee. Below are the revisions that will be made to the proposal: .02 Definitions. .02B(1) – Page 1 - A definition was added for "ANDA" numbers; .02B(14-1) – Page 3 - A definition was added for "NDA" numbers; .02B(21-1) – Page 5 – A definition was added for "UDI" numbers; .02B(21-2) – Page 5 – The definition of "virtual manufacturer" was expanded to include ownership of UDI numbers, as available. Additionally, a subparagraph was added that at no time does the virtual manufacturer take physical possession or store a drug or device. .03-1 Minimum Application Requirements for Virtual Manufacturers. *(some sections have been renumbered due to additions)* .03-1C – Page 15 – A section was added to the requirements for a virtual manufacturer, that meets certain criteria, requiring a list of UDI numbers, as available, associated with each device it distributes; .03D – Page 15 – This section was revised to require the provision of the facilities address; .03E – Page 15 – A section was added to the requirements for a virtual manufacturer, that meets certain criteria, requiring verification of current FDA registration for each contract manufacturing facility listed; .03G – Page 15 – This section clarified that if the contract manufacturer	Motion by Legislation/Regulations Committee to approve revisions to COMAR 10.34.22 as a result of the informal comments.. Motion seconded by M. Gavgani.	Motion was approved.

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		does not distribute into Maryland, the virtual manufacturer is required to provide a Maryland wholesale distributor permit number for whomever is distributing into Maryland; .03H – Page 15 – UDI numbers were added to this section; .03J – Page 15 – This section was rewritten for clarification purposes. It now reads "Provides a copy of existing licensure from the state in which it is located, if applicable," The Board would also like describe specific informal comments that did not result in revisions to the proposal and the Board's reasoning for not making those revisions: It was suggested to include in this chapter a Division of Drug Control (DDC) requirement that if a wholesale distributor is distributing controlled dangerous substances, it would be required to obtain a controlled dangerous substance permit from DDC. The Board will not be including a DDC requirement in the proposed Board regulations, but will make a note of it on the revised application. It was also requested that "devices" be removed from the entire chapter because the U.S. Prescription Drug Marketing Act of 1987 does not include devices and is referenced in the Maryland Wholesale Distributor Permitting and Prescription Drug Integrity Act (the "Act"). The Act clearly includes both prescription drugs and prescription devices. See Health Occupations Article, 12-6C-01(u), Annotated Code of Maryland where wholesale distribution is defined as the distribution of prescription drugs or <u>prescription devices</u> to persons other than a consumer or patient. To remove "devices" from this chapter would require a statutory revision. <u>Additional suggested revisions which were not recommended follows:</u> .02B(21-1)(a) - It was suggested to include in the definition of "virtual manufacturer" a manufacturer of a "DESI" prescription drug or other "grandfathered drug." The Board will not be including DESI drugs because it appears that DESI products are considered less effective than other marketed drugs and are being discontinued by manufacturers. .03B-1(3) – The designated representative and the immediate supervisor are required to request the appropriate entity in the applicant's state of		

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		resident to forward the results of the criminal history records check to the Board and the applicant. One entity that submitted an informal comment offered to make information on the FBI and various states' criminal background check processes available to the Board. The Board will take this offer under consideration to assist applicants. .03E(4) – A pharmacy warehouse that is not engaged in wholesale distribution is exempted from the surety bond requirement. It was suggested to broaden this to applicants that are publicly held companies. The Board will not be recommending this suggestion since the statute does not allow it. .03-1- A new section was suggested which would require a FDA monograph listing information if the applicant will be distributing a DESI product. Again, the Board will not be including DESI products in these regulations since it appears that DESI products are considered to be less effective than other marketed drugs and are being discontinued by many manufacturers. .03-1 – A new section was suggested which would require a listing of all prescription devices and proof that the devices are registered and listed with the FDA if the applicant intends to distribute any prescription devices. The Board will not add this suggestion since it would be over burdensome and may be of questionable value to the applicant's file. .03-1 – It was suggested to expand on the section which would require a statement affirming that the virtual manufacture does not contract the manufacture or distribution for drugs or devices other than those for which it owns the NDA or ANDA to include: • Other than a licensee of the NDA or ANDA approval holder; • Affirming that the virtual manufacturer does not contract the manufacture or distribution of a DESI prescription Drug; or • Other "Grandfathered Drug" for which it is considered to be the manufacturer. The Board does not believe this expansion is necessary and will not include DESI products as described above. .03-1 – It was suggested to add to the section which would require an		

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		attestation by the owner of the virtual manufacturer that it does not hold product to include owner's designee, officer, or member, if a limited liability company. The Board has determined that requiring the attestation by the "owner" is sufficient. .03-1 – It was suggested to add to the section which would require a copy of the existing licensure of an entity from the state in which it is located to, in the alternative, require an expressed exemption from licensure if the state in which it is located did not license the entity. The Board determined that this requirement might be difficult to obtain and unnecessary. .03-1 – It was suggested to add three new sections as follows: • Provide the front page and signature page of all contract manufacturing agreements and third party logistics agreements. • Provides the front page and signature page of the licensing agreement between the ANDA or NDA owner and the virtual manufacturer. • Provide digital copies of all labels of prescription drug products you wish to market in the state of Maryland. The Board determined that front and signature pages of a contract manufacturing agreement or a licensing agreement would not add significant information to the applicant's file. Finally, providing digital copies of all labels of drug products would be over burdensome and of questionable value to an applicant's file. Thank you again for your thorough reading of and informal comments to the proposed revisions to COMAR 10.34.22 Licensing of Wholesale Prescription Drug or Device Distributors. The draft regulations have been revised as described above and were approved at the October 17, 2012 Public Board Meeting for submission to the Department of Health and Mental Hygiene for approval and subsequent publication in the Maryland Register. Board approval requested for revisions to COMAR 10.34.22 as a result of the informal comments.		

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		FINAL DRAFT 10.34.22 092612 **The Board approved the proposal for publication.** **10.34.29 – Drug Therapy Management** **Holding for Board of Physician's approval of the proposal.** **10.34.33 –** Holding for Fed Regs . **10.34.36** – **Pharmaceutical Services to Residents in Assisted Living Programs and Group Homes -** Published September 21, 2012. Holding for expiration of 30 day comment period. **10.13. 01 – Dispensing of Prescription Drugs by a Licensee** Under consideration by the Practice Committee.		
III. Committee Reports A. Practice Committee	H. Finke, Chair,	**1)**Michelle McGovern, lawyer **12-403(f)(6) phone hours for the 6th day** **Draft Bd Response – Nonresident – phone hrs for 6th day** Thank you for contacting the Maryland Board of Pharmacy concerning clarification on Md. Health Occupations Code Code Ann. § 12-403(f)(6), which states: "A nonresident pharmacy shall, during its regular hours of operation, but not less than 6 days a week, and for a minimum of 40 hours per week, provide toll-free telephone service to facilitate communication between	Motion by Practice Committee to approve draft Board response to Michelle McGovern. Motion seconded by D. Taylor.	Motion was approved.

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		patients in this State and a pharmacist who has access to the patient's prescription records." If a pharmacy meets the 40 hours per week aspect of the requirement in five days, how much phone access must be provided on the sixth day? A pharmacist is required to be available by phone at a nonresident pharmacy to address Maryland patient's concerns and questions six days a week. So long as the patient is provided a toll-free telephone number that gives the patient access to a pharmacist six days a week, the specific hours each day are not considered as long as there is coverage by a pharmacist over the 6 days. **2)** Dr. Jennifer Gudeman, Ther-Rx Corporation **Compounding of hydroxyprogesterone caproate injections** **Draft Bd Response – Compounding – Hydroxyprogesterone** Thank you for contacting the Maryland Board of Pharmacy requesting that the Board notify Maryland pharmacists of the recent statements made by the U.S. Food and Drug Administration (FDA) regarding the compounding of hydroxyprogesterone caproate injections. The Board will not be honoring this request as it sees no reason why pharmacists may not compound this product. The FDA has stated: "In order to support access to this important drug, at this time and under this unique situation, FDA does not intend to take enforcement action against pharmacies that compound hydroxyprogesterone caproate based on a valid prescription for an individually identified patient unless the compounded products are unsafe, or substandard quality, or are not being compounded in	Motion by Practice Committee to approve draft Board response to Jennifer Gudeman, Ther-Rx Corporation. Motion seconded by D. Taylor. After discussion from Jennifer Gudeman, who attended the Board Meeting, the matter was referred back to the Practice Committee for further consideration.	

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		accordance with appropriate standards for compounding sterile products. As always, FDA may at any time revisit a decision to exercise enforcement discretion. ” <u>Dr. Jennifer Gudeman attended the meeting and pointed out that the letter utilized outdated information. She offered to send the Board the recent FDA statement. The Board send this response back to Practice for further consideration</u> **<u>3)</u>** Two phone calls concerning how long a pharmacist, working at a nonresident pharmacy that is in the reciprocity process, has to take the MPJE once approved to take the exam. As long as the pharmacist exercises due diligence in taking the MPJE as soon as possible, there is no specific timeframe in which the pharmacist has to take the exam. **<u>Draft Bd Response - SB 132 - timeframe for MPJE</u>** Thank you for contacting the Maryland Board of Pharmacy concerning the timeframe in which a reciprocating pharmacist, working at a nonresident pharmacy, may take the MPJE after submitting all applications and fees to the Board and NABP by October 1, 2012 to comply with SB 132 Health Occupations - State Board of Pharmacy – Jurisdiction Over Nonresident Pharmacies. There is no specific timeframe in which a reciprocating pharmacist, working at a nonresident pharmacy, would be required to take the MPJE. The Board expects reciprocating pharmacists, working at a nonresident pharmacy, to exercise due diligence and complete all outstanding requirements as soon as possible. **4) Dr. Yunus Thakur**	Motion by Practice Committee to approve draft Board response concerning timeframe in taking in which a non-resident pharmacist has to take the , MPJE exam once the pharmacist is approved to take the exam. Motion seconded by D. Taylor.	Motion was approved.

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		RFID tagging **Draft Bd Response – RFID tagging** Thank you for contacting the Maryland Board of Pharmacy concerning "radio frequency identification" (RFID) tagging of drug vials for a local hospital. Below is a description of your business plan: A hospital will prepare Emergency Drug Trays for in-house use and those drug trays consist of original manufacturer's injectable drug vials. All drugs are non-controlled. A company named 'KitCheck' has developed a machine which electronically can check trays for any error during the tray-making process. To use the system however, each drug vial will be attached with a RFID tag. The tag is drug-specific and contains necessary information of a particular drug agent such as name, NDC, expiration date, manufacturer, etc. You would procure RFID tags from KitCheck and the hospital (your customer) would deliver their drugs to you. Your job would be to attach the RFID tag on the vial send back the tagged-vial to the hospital. The tag would be attached on the original vial. If the vial comes (from the manufacturer) in a single-unit packet or box, the tag will be attached on the packet/box. The original packet/box would not be opened in any circumstances. Since you would be receiving prescription drugs (injectable drug vials) and then distributing those prescription injectable drugs vials back again to the hospital, you would be required to be licensed as a wholesale distributor, regardless of the length of time the drug vials are in your facility. If this facility is currently a Maryland licensed pharmacy, then you would have to determine if this activity accounts for more than 5% of the retail pharmacy's annual sales. If so, the pharmacy permit holder would have to apply for a wholesale distributor permit. You may also want to contact the U.S. Food and Drug	Motion by Practice Committee to approve draft Board response to Dr. Yuinus Thakur. Motion seconded by D. Taylor.	Motion was approved.

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		Administration as this activity may be construed as repackaging/labeling and other federal requirements may apply.		

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B. Licensing Committee	D. Chason Chair,	**1) Review of Pharmacist Applications: None** **2) Review of Pharmacy Technician Applications:** • Kathleen Harding - Applicant answered yes to question # 3 regarding surrendering or failing to renew a healthcare registration or license. Explanation: Choose not to renew her DE Nursing Assistant registration. Says she was no longer able to fulfill duties of her job. Recommendation is to approve application. **3) Review of Distributor Applications: NONE** **4) Review of Pharmacy Technicians Training Programs:** • Pharmacy Technician University from Pharmacist Letter – Recommendation is to approve program. **5) New Business:** • Donald Richard - Licensee would like a refund of the renewal fees paid as he was unable to renewal online. Applicant sent in letter stating he choose not to renew and requested his license to be placed on an inactive status, but attached his CE's and renewal fee, but no application. Information was processed and letter was sent to applicant requesting additional CE's. Recommendation is to deny refund request as it is an	Motion by Licensing Committee to approve application of Kathleen Harding. Motion was seconded by M. Gavgani. Motion by Licensing Committee to approve Pharmacy Technician University Program. With provision that the training program be managed by an approved Maryland training program which would provide the Maryland law aspect of the program. Motion was seconded by H. Finke. Motion by Licensing Committee to deny Donald Richard's request for a refund. Motion was seconded by D. Taylor	Motion was approved. Motion was approved. Motion to deny refund was approved with clari-fication that there is no inactive status.

Subject	Responsible Party	Discussion	Action Due Date (Assigned To)	Results
		administrative fee. • Letter from Respicare requesting waiver for having a MD licensed pharmacist on staff and an email from Rossanna Cielo with the same request. Recommendation is to write letter stating the Board's current interpretation on companies that sell prescription devices to individuals in their homes are required to be a licensed pharmacy. • **Drug Therapy Management Application** – Recommendation is to approve the revised program application. • **Sub-Committee Recommendation** - Licensing Committee recommendation to develop a sub-committee of Licensing and Practice to involve Office of Healthcare Quality, Board of Pharmacy and OHCQ in regulatory changes that need to be made on whether or not it makes sense to require DME companies that dispense only a few prescription devices to be pharmacies	Motion by Licensing Committee to inform Respicare and Rossanna Cielo that companies that sell prescription devices to individuals in their homes are required to be a licensed pharmacy. Motion was seconded by D. Taylor. Motion by Licensing Committee to approve Drug Therapy Management Application. Motion was seconded by L. Israbian-Jamgochian. Motion by Licensing Committee to approve sub-committee recommendation Motion was seconded by M. Gavgani. Motion was rescinded by D. Chason. Motion to rescind was seconded by D. Taylor. Motion by Licensing Committee to appoint a Task Force to review this matter. Motion was seconded by M. Gavgani.	Motion was approved. Motion was approved. . Motion to rescind was approved.

Subject	Responsible Party	Discussion	Action Due Date (Assigned To)	Results
C. Public Relations Committee	L. Bradley-Baker, Chair	Public Relations Committee Update – • The Board participated at the Baby Boomer Expo October 10 and 11, 2012 at the Timonium Fairgrounds and there was a tremendous turnout of over 10,000 people. Students participated from both the University of Maryland Eastern Shore School of Pharmacy and Notre Dame School of Pharmacy. Special thanks to Janet Seeds coordinated the event on both days. • The BOP assisted the Baltimore County Department of Health in recruiting pharmacists to participate in their Pharmacists Hotline to answer question about flu and immunizations. Eight pharmacists participated for 2 hours fielding over 40 phone calls. • The BOP annual CE Breakfast is scheduled Sunday, October 21, 2012 at the Raddison Hotel at Cross Keys beginning at 8:00 a.m. The topic is "Drug Shortages: Considerations for the Pharmacy Professional." At this point we have 112 registrants. The BOP will recognize four pharmacists that have 60 years of pharmacist's licensure. •		
D. Disciplinary	L. Israbian-Jamgochian Chair	Disciplinary Committee Update – No update this month.		
E. Emergency Preparedness Task Force	D. Taylor Chair	Emergency Preparedness Task Force Update – No update this month.		

Subject	Responsible Party	Discussion	Action Due Date (Assigned To)	Results
IV. Other Business & FYI	M. Souranis, President	M. Souranis reported on an article that appeared in the Daily Record titled, "Point of Care becomes Point of Contention." Five surgeons faced administrative hearings after an Injured Worker's Insurance Fund (IWIF) complaint. M. Souranis noted that physicians who practice under IWIF conditions and dispense pharmaceuticals are not required to adhere to the same standards and audits that pharmacies are required to adhere to.		
V. Adjournment	M. Souranis, Board President	The Public Meeting was adjourned at 11:53 a.m. At 11:42p.m. M. Souranis convened a Closed Public Session to conduct a medical review of technician applications. C. The Closed Public Session was adjourned at 1:00 P.M. Immediately thereafter, M. Souranis convened an Administrative Session for purposes of discussing confidential disciplinary cases. With the exception of cases requiring recusals, the Board members present at the Public Meeting continued to participate in the Administrative Session.	Motion by D. Chason, to adjourn the Public Board meeting pursuant to State Government Article 10-508)a)(13) and (7) for the purpose of engaging in medical review committee review deliberation regarding confidential matters in applications Meeting. The motion was seconded by L. Israbian-Jamgochian.	Motion was approved by the Board.